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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,642	02/22/2002	Robert J. Fitzsimmons	24004350.10022US	8163

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PATENT DEPARTMENT  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/080,642

**Applicant(s)**

FITZSIMMONS, ROBERT J.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 18-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 2-6 and 18-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 4/21/05 has been entered into the record.
- B. Claims 2-6 and 18-23 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Priority***

- A. The priority date for the present invention remains 2/22/02, the filing date of the instant application. While the provisional application (60/271,030) does discuss using VEGF and PEMF in general terms, it does not disclose the specific limitations, such as pulse and frequency.

### ***3. Claim Rejections - 35 USC § 112, second paragraph***

- A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' cancellation of, or amendments to the claims.

### ***4. Claim Rejections - 35 USC § 112, first paragraph, scope of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 2-6 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the frequency and pulse as depicted in Figures 10 and 11, does not reasonably provide enablement for the frequencies and pulses recited in claims 4, 18 and 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence

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of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants do not provide any guidance or working examples of methods using PEMF comprising the pulse and frequencies claimed. Figures 10 and 11 appear to have very specific spikes at certain frequencies, which appear to be approximately 10-fold less than that claimed. It would not be predictable to the artisan, given the data in the specification (Figures) that a frequency of 10-fold higher would produce the desired results. Furthermore, no specific pulse can be found in the specification (Examples). For these reasons, undue experimentation would be required to practice the claimed invention.

***5. Claim Rejections - 35 USC § 112, first paragraph, new matter***

A. Claims 2-6 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the claims to recite pulses of 5.5 and 26 msec and frequencies of 3800-3900. However, these exact values and ranges could not be found in the specification. Applicants are required to point out exactly where in the specification support for these amendments can be found. **This is a new matter rejection.**

***6. Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 6 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have not defined "substantially similar" or the entire limitation "substantially similar to cell growth that occurs when a VEGF receptor is activated by a VEGF ligand."

**7. Claim Rejections - 35 USC § 102**

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' amendments to the claims. The claims now recite specific pulse times and frequencies. The general concept of PEMF on bone is clearly well-known in the art. Furthermore, as argued by the Examiner in the Office Action mailed 12/16/04, VEGF receptors are found inherently on bone. However though it would be expected that the methods recited in the cited prior art would stimulate VEGF receptors, the Examiner cannot make a prima facie case (whether inherent under 35 USC 102 or obvious under 35 USC 103) that the exact conditions (pulse and frequency range) recited in the present claims would have been chosen from the general knowledge in the art. The cited prior art used pulses and frequencies much less than those of the present invention. While George et al. ('069) do teach that the frequency range of the electromagnetic spectrum is between 1000 Hertz and 1000 MegaHertz, no motivation is given in either George or the other prior art documents to point specifically to the range of 3800 – 3900 Hz as claimed in the present invention, or for 5.5 or 26 msec. As an aside, it is noted that George teach microseconds in column 12, not milliseconds as stated by Applicants, making George even less likely prior art against the present invention.

**8. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yen-Patton et al. (J. Cell. Physiol.). The claims recite activating VEGF in endothelial cells or bone with a PEMF frequency of 3800-3900 Hz and a burst period of approximately 5.5 msec. Yen-Patton teach stimulating angiogenesis in both vascular endothelial cells and bone using PEMF, as claimed in the present invention (Abstract and first paragraph of the Introduction). Yen-Patton also teach a frequency range of 15-4000 Hz, which encompasses the range of the present invention (page 45, first column, first paragraph). Yen-Patton also teach a burst period of 5 msec. This period would meet the limitation of "approximately 5.5 msec."

Though Yen-Patton do not teach a specific frequency of 3800-3900 Hz, it would have been obvious to the artisan to establish an ideal frequency range in order to maximize the effect of PEMF on endothelial and bone cells. In absence of evidence to the contrary, it would be expected that stimulating

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VEGF receptor with PEMF would have the same effects as stimulating the receptor with a ligand, since the receptor would be entering an activated state in both cases. Furthermore, Applicants have not defined "substantially similar" or the entire limitation "substantially similar to cell growth that occurs when a VEGF receptor is activated by a VEGF ligand."

### **9. Conclusion**

A. No claim is allowable.


### ***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on T-F 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman  
Primary Examiner  
Art Unit 1647

  
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